IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., ROCHESTER DRUG CO-OPERATIVE, INC., MEIJER, INC., MEIJER DISTRIBUTION, INC., AMERICAN SALES COMPANY, LLC, WALGREEN CO., SAFEWAY INC., SUPERVALU INC., and HEB GROCERY CO. LP, et al.,	:	
Plaintiffs,	:	**Civ. No. 12-3824 CONSOLIDATED**
v.	:	**INDIRECT PURCHASER ACTION**
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	:	
Defendants.	:	

APPENDIX IN SUPPORT OF DEFENDANT WARNER CHILCOTT'S OPPOSITION TO INDIRECT PURCHASER PLAINTIFFS' AMENDED MOTION FOR CLASS CERTIFICATION

PUBLIC REDACTED VERSION

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FACTUAL BACKGROUND

A. The Markets in which Doryx Competes Are Crowded with Brand, Generic, and OTC Drug Alternatives and Are Highly Competitive

Doryx—the branded form of delayed-release doxycycline hyclate—is an antibiotic in the tetracycline class of antibiotics. Doryx is indicated for the treatment of a variety of conditions, but physicians primarily prescribe Doryx for the treatment of *acne vulgaris*. Over 500 prescription and over-the-counter products are available in the United States for the treatment of *acne vulgaris*, making that market both crowded and highly competitive. The prescription segment of these treatments includes topical medications such as (a) retinoids (*e.g.*, Retin-A and Avita), (b) antibiotics (*e.g.*, clindamycin), and (c) benzoyl peroxide, and oral medications such as (a) antibiotics (*e.g.*, erythromycin and tetracyclines), (b) isotretinoin (*e.g.*, Accutane and Mylan's Amnesteem), and (c) hormonal therapies (*e.g.*, oral contraceptives and spironolactone).[1] The narrower tetracycline class of antibiotics includes doxycycline hyclate in both delayed release (*e.g.*, Doryx and generics) and immediate release forms (*e.g.*, Vibramycin, Periostat, and generics), doxycycline monohydrate (*e.g.*, Adoxa, Monodox, Oracea, and generics), and minocycline in both immediate and extended release (*e.g.*, Dynacin, Solodyn, and generics) forms.[2] [redacted].[3] [redacted]

[1] Report of James J. Leyden, Oct. 18, 2013, (Ex. 1) (Exhibit 1 includes all expert declarations and expert reports cited in this Opposition Brief)) ¶ 47–86; Report of Guy Webster, Oct. 18, 2013, (Ex. 1) ¶ 27–29, 32. *See generally* Gollnick H, Cunliffe W, Berson D, et al. Management of Acne: a report from a Global Alliance to Improve Outcomes in Acne, J AM ACAD DERMATOL. 49:S1–S37 (2003) (Ex. 2).

[redacted]

[redacted] In the narrower tetracycline oral antibiotic segment of the market, Doryx on average has accounted for less than 4% of new prescriptions.[5]

Physicians regularly substitute one anti-acne treatment for another based on their clinical assessments of their patients' needs.[6] [redacted] Competition between and among products within the anti-acne market is correspondingly fierce.[9]

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[4] [redacted]

[5] Expert Report of Sumanth Addanki, Oct. 18, 2013, (Ex. 1) Attachment 10b, pg. 1 (showing shares of new prescriptions of doxycycline and minocycline oral antibiotic products by year from 2005 to 2013). Even when taking into account total prescriptions during the class period, Doryx still accounts for less than 15% of prescriptions.) Addanki Rep., Attachment 10a, pg. 2; [redacted] Defendants' expert Sumanth Addanki has defined the relevant market to include "oral tetracyclines used for the treatment of acne, including doxycycline monohydrate, doxycycline hyclate, and minocycline, in branded and generic forms" for purposes of his opinion that Warner Chilcott could not have exercised monopoly power. Addanki Rep. ¶¶ 120–21.

[6] Leyden Rep. ¶ 32; Webster Rep. ¶¶ 25–26, 29; Addanki, Rep. ¶ 45.

[7] [redacted]

[9] Addanki Rep. ¶¶ 40-50, 60-119 (discussing the ways in which Warner Chilcott competed against other oral antibiotics used to treat acne at the physician, pharmacy, payer, and patient levels); S*ee, e.g.*, Webster Rep. ¶ 36

Discovery from third parties confirms the vigorous competition in the broad and crowded marketplace for anti-acne medications. Manufacturers of other branded antibiotics viewed Doryx as a strong competitor. [redacted][10] [redacted][11] Documents and testimony from third party payers demonstrate similar views on the market for *acne vulgaris*, showing that multiple other drugs (*e.g.*, generic

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("Medicis, which manufactured Dynacin and currently manufactures Solodyn, both minocyclines, and Warner Chilcott vigorously compete for dermatologists to write their branded prescriptions."); [redacted]

[11] *See, e.g.*, [redacted]

immediate release doxycycline hyclate, other generic doxycyclines, and minocyclines) are clear substitutes for Doryx and are just as effective for patients.[12]

For these reasons, Warner Chilcott has been acutely aware of its competition in the anti-acne space as it worked to market Doryx against existing competitors and develop and improve Doryx for the future.[13] Many of the improvements to the Doryx product were in response to improvements and changes made by branded competitors, including Adoxa and Solodyn, such as moving to a tablet, introducing new strengths, or introducing scoring.[14] In short, brand competition affected the innovation of the Doryx products.

B. Warner Chilcott Was a Relatively Small, Specialized Pharmaceutical Company Committed to the Doryx Franchise Even in the Face of Widespread Generic Competition for Acne Treatment

At all times relevant to this litigation, Warner Chilcott has been a modestly-sized specialty pharmaceutical company with a product portfolio consisting of nine principal products

including Doryx, Warner Chilcott's flagship dermatology product.[15] Warner Chilcott competes in this marketplace with some of the largest and most sophisticated companies in the world, including Pfizer Inc. ($59.0 billion in annual revenues)[16] and Novartis AG ($56.7 billion in annual revenues).[17] Mayne is an even smaller specialty pharmaceutical company with a product portfolio of six key products and annual revenues of $51.9 million.[18] Warner Chilcott has been selling Doryx for sixteen years, and has remained committed to marketing and improving Doryx, even after Sandoz launched generic 75 and 100 mg Doryx capsules in July 2006[19] and Mylan launched generic Doryx 75 mg and 100 mg tablets in late 2010, and launched generic Doryx 150 mg tablets in April 2012.[20]

Warner Chilcott employs a national dermatology sales force responsible for promoting and detailing Doryx to dermatologists, physicians, and other healthcare providers. Warner Chilcott also competes on price. It continues to maintain its customer loyalty card program for Doryx, which provides financial assistance to patients to help cover their insurance co-pay for Doryx.[21] Warner Chilcott also provides rebates to certain third party payers to ensure that those

[15] Warner Chilcott, PLC 2013 Form 10-K financial report, at 1 (Ex. 40). On October 1, 2013, Warner Chilcott was acquired by Actavis, a global pharmaceutical company. Press Release, Actavis, Inc., Actavis Completes Warner Chilcott Acquisition, Oct. 1, 2013, *available at* http://ir.actavis.com/phoenix.zhtml?c=65778&p=irol-newsarticle &ID=1860196.

[16] Pfizer Inc. 2012 Form 10-K Financial Report at 15 (Ex. 41).

[17] Novartis AG 2012 Form 20-F at 4 (Ex. 42). PharmaDerm, which markets and sells Adoxa (doxycycline monohydrate), is a division of Fougera Pharmaceuticals, Inc., which is an affiliate of Novartis AG. *Id.* at 75.

[18] Mayne 2012 Annual Report at 4, 8 (Ex. 43).

[19] [redacted]

[21] [redacted] Addanki Rep. at ¶¶ 98-119 (discussing how Warner Chilcott and other branded competitors compete on price via patient coupon programs); [redacted]

insurance plans will include Doryx as a covered drug.[22] As a result of these efforts, and [redacted] Warner Chilcott was able to retain more than 60 percent of the total filled prescriptions for doxycycline hyclate DR 150 mg tablets through most of 2013 (up until the launch of the 200 mg Doryx tablet) even after the launch of the Mylan generic in May 2012.[24]

Warner Chilcott continues to expend significant R&D resources on the expansion and improvement of its dermatology products.[25] These investments have allowed Warner Chilcott to bring to market multiple new FDA-approved versions of the Doryx product over the past sixteen years, each providing medical and/or therapeutic benefits to patients, physicians, and payers.[26] [redacted]

Warner Chilcott increased its sales force to approximately 70 representatives by the end of 2007. Warner Chilcott 2012 Form 10-K at 9 (Ex. 40).

[22] [redacted]

[23] [redacted]

[24] Q1 2013 Warner Chilcott Earnings Call Transcript (Ex. 55) at 4; Mayne 2012 Annual Report at 8 (Ex. 41) ("Despite [the launch of a generic product in May 2012 by Mylan], IMS Health data shows prescription volumes for Doryx® 150mg tablets sold by Warner Chilcott . . . are not following a typical generic substitution curve and have only fallen approximately 35% since the entry of generic competition and stabili[z]ed across June, July and August. Over this period Warner Chilcott have maintained their national Doryx® sales force and customer loyalty card."); *see also* Declaration of Pierre-Yves Cremieux on End-Payer Class Certification, May 16, 2013 at ¶ 97 ("Cremieux Decl.").

[25] Warner Chilcott 2012 Form 10-K at 13 (Ex. 38); [redacted]

[26] *See, e.g.*, Webster Rep. ¶ 48–114; [redacted]

[redacted]

C. Warner Chilcott's Doryx Strategy Was to Compete through Product Improvements Even in the Face of Branded and Generic Competition

F.H. Faulding & Company Limited (Mayne's predecessor company) obtained FDA approval to market the first Doryx product (100 mg capsules) in the United States in 1985 and launched the capsule—without patent protection and open to generic competition[30]—that same year.[31] [redacted] Drawing on the sales tactics of branded competitors such as Dynacin, Warner Chilcott developed and implemented a plan to market the Doryx 100 mg (and later 75 mg) capsule to dermatologists, utilizing a dermatology sales force, a specialized team knowledgeable about issues related to dermatology and focused on maintaining good relationships with dermatologists, particularly those with a history of preferring brand products.[33] Through these precision marketing efforts, annual revenues from the Doryx capsules increased,

[27] [redacted]

[29] [redacted]

[30] [redacted]

[31] [redacted]

[32] [redacted] Mayne continues to manufacture Doryx for Warner Chilcott to sell in the United States.

[33] [redacted]

reaching approximately $70 million in 2004, despite significant competition from other anti-acne products.[34]

1. The Need for 75 mg Capsules

[redacted] The 75 mg capsule was approved by the FDA in August 2001 and launched by Warner Chilcott in January 2002—again with no patent protection and open to generic competition.[38]

2. The Development of Doryx Tablets

Warner Chilcott began considering a tablet form of Doryx well before it received FDA approval for the 75 mg Doryx capsule [redacted] Defendants' decision to pursue and eventually bring to market a tablet form of Doryx was motivated by

[34] [redacted]
[35] [redacted]
[36] *Id.*; [redacted]
[37] [redacted]
[38] [redacted]
[39] [redacted]

certain challenges presented by capsule products as well as opportunities associated with a tablet version, including:

- **Capsule safety concerns**. In the late 1990's global regulators were raising concerns and considering withdrawal of doxycycline hyclate capsules as a result of the risk of esophageal injuries.[41] Pharmacists also recognized the issue. [redacted] Defendants' adverse events reports also reflected incidences of pill induced esophagitis.[43] [redacted] In the United States, Warner Chilcott was served with a products liability complaint claiming esophageal injury from the use of Doryx.[46]

[41] [redacted] In 1997, the French Commission d' Autorisation de Mises sur le Marché (l'AMM), which advises France's drug safety agency on drug-approval requests, surveyed 81 cases of esophageal injuries resulting from the ingestion of tetracycline capsules— 6% of these involve doxycycline capsules. As a result, the I'AMM asked manufacturers to replace all tetracycline capsules with a tablet form within 2 years. V. Champel (1997), *Esophageal Injury*, at 589. Then the Swedish Medical Products Agency (MPA) opened an inquiry. [redacted]

[42] [redacted]

[43] *See, e.g.*, [redacted] see Nostrant Rep. ¶¶ 47-63 (Ex. 1) (reviewing Doryx capsule Med Watch Reports discussing esophageal injuries and cases from his own practice); [redacted]

The introduction of a Doryx tablet was intended to—and in fact did—eliminate these concerns regarding product safety, potential withdrawal due to regulatory action (e.g., by the FDA), and potential additional lawsuits because tablets do not present the same "sticking" issues as capsules do.[47] Indeed Defendants' expert Dr. Nostrant showed a nine-fold reduction in esophageal and possible esophageal adverse events reported with Doryx tablets when compared to Doryx capsules.[48]

- **Capsule stability concerns**. In addition to the esophageal issues, the Doryx capsule formulation demonstrated dissolution stability issues that affected shelf life.[49] The Defendants sought to resolve the risk of dissolution-stability failures through the tablet formulation.[50] Because of the importance of a long shelf life and the risks of recall, the Defendants looked to address stability concerns through a new invention.[51]

[redacted] The invention by which Defendants addressed their stability concerns was

[47] [redacted] Nostrant Rep. ¶¶132–64 (discussing regulatory concerns and tablet development); Perkins Rep. ¶¶ 43–89 (discussing regulatory concerns and tablet development); Robbins Rep. ¶¶ 55 (stating that products liability lawsuits "impose risks and costs for a pharmaceutical company and raise reputational issues"); V. Champel (1997), *Esophageal Involvement after Tetracycline Ingestion*, *in* THÉRAPIE (1997) (Ex. 91) (concluding that "[e]sophageal injury is 22 times more frequent with capsules than with tablets"); [redacted]

[48] Nostrant Rep. Ex. A; *see also*.Nostrant Rep. ¶¶ 64–92, Ex. A–G.

[redacted]

embodied in U.S. Patent No. 6,958,161 (the "'161 Patent") issued in 2005. This patent invention was able to be used in the new Doryx tablets.[53]

- **Branded Competition**. Defendants' pursuit of a Doryx tablet was also a response to branded competitors and a way to meet competition.[56] In addition, Defendants' competitors——were using the esophageal sticking issue as a point of differentiation for their products and marketing the esophageal irritation/ulceration issues against Defendants.[58]

- **Potential for future improvement (scoring)**. One of the important benefits of pursuing a tablet form of Doryx was the potential for achieving greater dosing flexibility in the future by developing scored tablets that could be subdivided by the

[53] *Warner Chilcott Labs. v. Impax Labs.*, No. 2:08-cv-06304 (WJM) 2012 WL 1551709, at *4 (D.N.J. Apr. 30, 2012).

[56]

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[58]

[60]

> patient into two or three smaller doses. Capsules, unlike tablets, cannot be scored and can provide only a single full dose.[61] Here, the utilization of a pellet-in-tablet formulation allowed for scoring of delayed-release tablets. Typically a delayed-release tablet product with the coating on the outside could not be scored because any breaking of the tablet would destroy the delayed-release coating.[62]

Defendants submitted an NDA seeking FDA approval for marketing Doryx 75 mg and 100 mg tablet products incorporating patented new technology in April 2004, received approval in May 2005, and launched the approved 75 mg and 100 mg tablets in August 2005.[63] The approved Doryx tablets had a shelf-life of 24 months.[64] After the launch, Warner Chilcott promoted the new, improved Doryx tablets over the old Doryx capsules and stopped marketing the capsules.[65]

[redacted]

[61] [redacted]

[62] Expert Report of Lisbeth Illum, October 18, 2013 ¶ 197 ("More notably, the utilization of a bead-in-tablet formulation allowed for scoring of delayed-release tablets, which, in my opinion, is an innovation in and of itself.").

[63] [redacted]

[65] *See* Expert Report of Pierre-Yves Cremieux, October 18, 2013 ("Cremieux Merits Rep."), Ex. 1 (timeline of Doryx and generic Doryx products); [redacted]

[66] [redacted] *see also* Howard Decl. (Ex. 45) ¶ 24; Federal Register /Vol. 73, No. 245, at 77723 (December 19, 2008) (Ex. 110) (listing "DORYX (doxycycline hyclate) Delayed-Release Capsules, EQ 75 mg and 100 mg base" and noting "The Food and Drug Administration (FDA) has determined that the eleven drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.").

[redacted]

3. Labeling for Administration with Applesauce

[redacted] The ability to sprinkle the contents of a tablet or capsule over applesauce provides for easier administration to patients who have difficulty swallowing pills.[70] It also allows for the wide availability and easy administration of Doryx to children and the elderly, including as a recommended dosage form in the event of an anthrax attack.[71]

In response to this feedback, [redacted]

[redacted]

[68] [redacted] *see also* Laxma R. Nagavelli et al., Analysis of Bead Sizes for MR Capsules Labeled for Sprinkle, 11 *AAPS PharmSciTech* 1508, 1508 (2010) (Ex. 115) ("It may be difficult for aged persons to swallow tablets or capsules, or for children who may be difficult to mediate because they are unable or unwilling to swallow tablets or capsules. This leads to poor compliance or even noncompliance with treatment and thus has a negative impact of the effectiveness of the treatment."); Monali Bhosle, Joshua S. Benner, et al., "Difficult to swallow: patient preferences for alternative valproate pharmaceutical formulations," 3 *Patient Preference and Adherence* 161, 162 (2009) (Ex. 116) ("A 2003 representative survey of US adults (N=679) regarding difficulty swallowing pill-form medications found that approximately 40% of respondents had experienced difficulty swallowing pills.").

[71] FDA, Stability and Dose Uniformity of Doxycycline Solid Dosage Tablets Ground and Mixed in Food or Drinks (last updated on Feb. 25, 2010), *available at* http://www.fda.gov/Drugs/Emergency Preparedness/BioterrorismandDrugPreparedness/ucm130999.htm ("In order to give these drugs to children in an emergency, the solid dosage forms need to be ground and mixed with appropriate food/drinks."); [redacted]

[redacted]

As with the launch of tablets, the applesauce labeling change, while providing significant benefits over previous labels that did not allow for administration of Doryx over applesauce, [redacted]

In fact, [redacted][4] Moreover, generic manufacturers could have easily anticipated that Warner Chilcott would seek labeling for administration of Doryx tablets with applesauce, as it had for Doryx capsules.

4. 150 mg Strength and Scored Tablets to Increase Dosing Options

Although the introduction of a tablet version of Doryx and the applesauce labeling

[redacted]

[redacted]

[redacted]

approvals represented significant improvements with respect to the safety, dissolution profile, and ease of administration of the Doryx product, Defendants understood that additional improvements would be necessary in order to grow the Doryx franchise and to remain relevant in the competitive U.S. acne market. In particular, Warner Chilcott recognized that it needed to provide physicians with increasingly efficient and flexible dosing options if it was going to meet the needs of the market, especially in light of new competitor products.[75] It began to explore the possibility of scored 75 and 100 mg tablets and to develop a 150 mg scored tablet in or around 2007.[76]

Defendants received FDA approval of the supplemental NDAs for their 75, 100, and 150 mg scored tablets in March 2009, February 2009, and June 2008, respectively.[77] These scored tablets provided myriad benefits,[78] including:

- **Increased flexibility in dosing**. Scored tablets benefit both patients and physicians by allowing greater flexibility in selecting a proper dosage and regimen for the patient, as scoring allows physicians to alter a regimen or dosage without having to force patients to throw away unused pills or to finish them before changing a regimen.[79] Greater flexibility in dosing is particularly beneficial in treating acne,

[redacted]

[78] *See* Guidance for Industry: Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation, U.S. FOOD AND DRUG ADMINISTRATION (2013) (Ex. 127); Guidance for Industry Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation U.S. FOOD AND DRUG ADMINISTRATION (2011) (Ex. 128); Pharmaceutical Sciences Scoring Configuration of Generic Drug Products, MANUAL OF POLICIES AND PROC. 5223.2 (1995) (Ex. 129).

[79] *See, e.g.*, Leyden Rep. ¶ 83–86; Webster Rep. ¶ 81–96.

which often requires a course of treatment with varying dosages over time.[80] The 150 mg scored tablet also provided physicians with the ability to prescribe a QD (once a day) dose of Doryx.[81]

- **Increased ease of swallowing**. Another benefit of scored tablets was the opportunity for patients to break tablets more easily into smaller pieces for additional ease of swallowing.[82]

- **Alleviation of weight variation**. When unscored tablets are broken, there is no guarantee that each divided part of the tablet contains an equal distribution of the drug ingredients. Scored tablets significantly reduce this problem by ensuring that each divided part contains the same amount of ingredient, providing greater accuracy and consistency in a treatment regime.[83]

- **Increased efficiency and lower patient co-pays**. Because scored tablets allow for a single prescription to satisfy step-down dosing regimens, the introduction of scored Doryx tablets allows for lower co-pays (for fewer transactions), reduced managed care costs, and fewer trips to the pharmacy.[84]

- **Meeting competition with closest branded rivals**. In November 2005, Bradley Pharmaceuticals launched a 150 mg scored Adoxa tablet (the first scored doxycycline tablet), and Medicis launched Solodyn (an improved version of Dynacin) shortly thereafter.[85] [redacted]

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[80] *See, e.g.*, Webster Rep. ¶ 94, 101 (stating that "treatment regimens of acne patients are highly individualized" and "there are patients who fare well from titrating up in 50 mg increments, others who do well from titrating down in 50 mg increments").

[81] [redacted]

[82] *See* [redacted]; Webster Rep. ¶ 18; Nostrant Rep. ¶ 97; Perkins Rep. ¶ 96–101.

[83] Illum Rep. ¶ 41 ("If a tablet is scored, it must meet additional testing to show that the doses that result from the score are also bioequivalent, ensuring intended dosing.").

[84] [redacted] Cremieux Merits Rep. ¶ 24; Nostrant Rep. ¶ 98; *see also* Randall S. Stafford & David C. Radley, The Potential of Pill Splitting to Achieve Cost Savings, 8 *Am. J. Manag. Care* 706, 706 (2002) (Ex. 132); Kimberlee Roth, Maximize Your Drug Plan: How to Save Money Without Sacrificing Safety, NEUROLOGY NOW 28, 31 (Nov./Dec. 2008) (Ex. 133); Hae Mi Choe et al., Impact of Patient Financial Incentives on Participation and Outcomes in a Statin Pill-splitting Program, 13 *Am. J. Manag. Care* 298, 298 (2007) (Ex. 134); United Healthcare, Half Tablet Program, 2007, *available at* http://worldclassbenefits.com/fms/pdf/Half%20Tablet%20program.pdf ("Our Half Tablet Program provides an opportunity for you to reduce your prescription medication copayments or coinsurance by using doublestrength tablets and splitting them in half.").

[85] [redacted] Press Release, Medicis Announces FDA Approval of SOLODYN (May 8, 2006), *available at* http://www.globenewswire.com/newsarchive/mrx/pages/news_releases.html?d=97861.

[redacted] Further, other branded doxycycline products, such as Oracea and Adoxa, were available in lower dose ranges.[87] The introduction of scored versions of 75, 100, and 150 mg Doryx tablets therefore allowed Warner Chilcott to compete with these branded competitor products.

5. 150 mg Dual-Scored Tablets

In September 2011, Warner Chilcott launched a dual-scored version of the Doryx 150 mg tablet and made the decision to withdraw the single-scored 150 mg Doryx tablets from the market.[88] The Doryx 150 mg dual-scored tablet, which can be separated into three 50 mg pieces, allowed Warner Chilcott to continue to provide flexible dosing options while only having to manage and market one line of inventory.[89]

The introduction of the single-scored or dual-scored Doryx tablets [redacted] certainly did not prevent any generic pharmaceuticals company from bringing a generic Doryx tablet to market. Mylan launched multiple generic tablets, in January 2011 (75 mg and 100 mg tablets) and April 30, 2012 (150 mg tablets).[90]

6. 200 mg Tablets

In April 2013, Defendants received FDA approval of a 200 mg Doryx tablet, which Warner Chilcott introduced in July 2013.[91] (Plaintiffs' brief incorrectly states that this approval

[86] [redacted]

[87] [redacted]

[88] [redacted]

[89] *See* Leyden Rep. ¶ 83 ("[O]ne prescription of Doryx dual-scored 150 mg could be used throughout the patient's entire course of therapy.").

[90] *See* Cremieux Merits Rep. Ex. 1 (timeline of Doryx and generic Doryx products). Because of patent litigation surrounding the introduction of 150 mg generic Doryx tablets, Mylan introduced its 150 mg product on April 30, 2012, the day the patent decision came out. *Mylan Launches First Generic Version of Doryx® 150 mg*, Apr. 30, 2012, *available at* http://investor.mylan.com/releasedetail.cfm?ReleaseID=668717.

[91] Press Release, Warner Chilcott Announces FDA Approval of Doryx® Delayed-Release 200 mg Tablets (Apr. 12, 2013), *available at* http://ir.wcrx.com/releasedetail.cfm?ReleaseID=756218; Q1 2013 Warner Chilcott Earnings Call Transcript at 7 (Ex. 59).

remains pending.)[92] In addition to the indications for acne and other conditions provided on the prior Doryx label, the 200 mg tablet provides additional benefits of a newly approved treatment regime for chlamydia (once-a-day rather than b.i.d. (twice-a-day dosing)) not previously offered to patients, a 200 mg single tablet Doryx dosing option, and increased flexibility in dosing.[93] Chlamydia is a prevalent, sexually-transmitted disease that can cause serious complications including infertility. Warner Chilcott continues to sell both the 150 mg dual scored and the 200 mg versions of its tablets.[94]

[92] Mem. of Law in Support of Indirect Purchaser Plaintiff's Amended Mot. for Class Cert., Dkt. No. 449 (Jan. 7, 2014), at 17 ("Plaintiffs Amended Brief"). Plaintiffs also incorrectly state that "Defendants are also working on Doryx calcium and a 150 mg capsule." Id at 17–18. The documents cited for this proposition are from, at the latest, two years ago, and their reference to "Doryx calcium" is simply wrong. [redacted]

[93] [redacted] Q1 2013 Warner Chilcott Earnings Call Transcripts at 7 (Ex. 59); Warner Chilcott Prescribing Information: Doryx® (doxycycline hyclate delayed-release tablets), 80 mg, 100 mg, 150 mg, and 200 mg for Oral use § 2.1, (Revised Apr. 2013) *available at* http://www.wcrx.com/pdfs/pi/pi_doryx_200.pdf.

[94] Q1 2013 Warner Chilcott Earnings Call Transcripts, at 10 (Ex. 59) ("Doryx 150 will continue to be on the market. It is a product that has done well and we think will continue to do well. We're very excited about the prospects, though, of adding in the Doryx 200 as a new option out there and so we're looking forward to that and that starts in July.").

Respectfully submitted this 31st day of January, 2014.

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CERTIFICATE OF SERVICE

I, Jack E. Pace III, hereby certify that on January 31, 2014, I caused true and correct copies of the Appendix In Support Of Defendant Warner Chilcott's Opposition to Indirect Purchaser Plaintiff's Amended Motion for Class Certification to be served by electronic mail and FTP server upon all counsel of record.

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